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| 08/238,405      | 05/05/94    | CAPON                | D CELL5.3           |

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EXAMINER

HAYES, R

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

09/08/98

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

08/238 405

Applicant(s)

Capom et al

Examiner

J. Hayes

Group Art Unit

1645

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☐ Responsive to communication(s) filed on 6/15/98.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 57, 59, 64-65, 67, 69, 71 is/are pending in the application.
- ☐ Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 57, 59, 64-65, 67, 69, 71 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☒ Notice of References Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

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## **DETAILED ACTION**

### ***Transitional After Final Practice***

1. Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's first submission after final filed on 06/15/98 has been entered.

2. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1645.

3. The rejection of claim 59 under 35 U.S.C. 112, second paragraph, is withdrawn due to the amendment of the claim.

4. The provisional rejections of claims 57-61 & 64-69 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 & 29-35 of co-pending application 08/125,038 and over claims 1-5, 7-15, & 17-18 of co-pending application 08/465,652, are withdrawn due to either the cancellation of claims, due to 08/465,652 now being abandoned, or due to 08/125,038 being directed to nucleic acids.

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5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Applicants' arguments filed 06/15/98 as paper # 26 have been fully considered but they are not deemed to be persuasive.

7. Claims 64-65, 67, 69, as well as new claim 71, are again rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 5,359,046, for the reasons made of record.

8. Claims 65 & 69 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The state of the art is such that all cells intrinsically contain Class I Major Histocompatibility Complex antigens. Moreover, the specification fails to provide guidance on how one skilled in the art can obtain such cells "wherein said cell is substantially free of surface expression of at least one of Class I or Class II MHC antigens" (i.e., as it relates to claim 69). Thus, one skilled in the art could not practice this aspect of Applicants' invention without undue experimentation to discover how to make this embodiment of Applicants' invention.

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Similarly, the state of the art at the time of filing Applicants' invention (i.e., 1991) was such that hematopoietic stem cells could not be isolated as a pure population of cells, and it was unknown how to obtain such. Moreover, the specification fails to provide guidance on how one skilled in the art can obtain such an isolated population of pure hematopoietic stem cells (i.e., as it relates to claim 65). Therefore, one skilled in the art could not practice this aspect of Applicants' invention without undue experimentation to discover how to make this embodiment of Applicants' invention. Thus, these claims are not enabled at the time of filing the instant application.

9. Claim 64 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is ambiguous what "protein" is being referenced, in that "chimeric proteins" and "proteins on the surface of a cell" are both recited in the claim.

10. Claim 67 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite because it is unclear what the metes and bounds for "substantially free" entail. Further, it is ambiguous how T lymphocytes can be free of MHC antigens when they intrinsically contain these antigens.

11. Claims 57, 64, 67, 69 & 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Gross et al.

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Gross et al. teach a chimeric membrane bound T-cell receptor protein (i.e., a tyrosine kinase; as it relates to claim 71) by removing the TcR V domain and replacing it with an antigen binding domain from a single chain antibody V domain (pg. 10025; as it relates to claim 57). Gross' chimeric protein comprises a signal/leader sequence and an extracellular C region that is naturally joined to the transmembrane domain, as well as a cytoplasmic domain which transduces a signal to induce T-cell proliferation, interleukin production and target cell lysis (pgs. 10024-10025, Fig. 1; as it relates to claim 57). This chimeric protein is expressed following transfection into murine cytotoxic T-cell lymphocyte hybridomas (i.e., mammalian cells that inherently no longer containing Class II MHC antigens; as it relates to claims 64, 67 & 69; absent evidence to the contrary).

12. Claims 57, 64, 67, 69 & 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuwana et al.

Kuwana et al. teach a chimeric membrane bound T-cell receptor protein (i.e., a tyrosine kinase; as it relates to claim 71) by replacing the TcR-derived V domain with the antibody/Ig-derived V domain (i.e., an antigen binding domain of a single chain antibody; pg. 961; as it relates to claim 57). Kuwana's chimeric protein comprises a signal/leader sequence of Ig V and an extracellular region of the TcR-derived C domain that are naturally joined to the transmembrane domain, as well as a cytoplasmic domain which transduces a signal to increase cytoplasmic calcium concentrations (pgs. 960-964, Figs. 1 & 2; as it relates to claims 57). This chimeric

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protein is expressed following transfection into human EL-4 cells (i.e., cytotoxic mammalian T-cells inherently not containing Class II MHC antigens; as it relates to claims 64, 67 & 69; absent evidence to the contrary).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.  
August 28, 1998

  
**PAULA K. HUTZELL**  
**SUPERVISORY PATENT EXAMINER**